

Attorney Docket No.: KUZ0030US.NP  
Inventors: Toshimitsu et al.  
Serial No.: 10/577,746  
Filing Date: April 27, 2006  
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#### REMARKS

Claims 1-12 are pending in the instant application. Claims 1-12 have been amended. Claims 1, 9 and 10 have been amended. New claims 13 through 22 have been added. Support for these amendments is provided in the specification at page 8, lines 20-25, pages 10-12, page 15, line 25, page 19, lines 7-8 and page 24, line 8. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

#### **I. Information Disclosure Statement**

The Examiner suggests that the Information Disclosure Statement submitted April 27, 2006 fails to comply with the provisions of 37 C.F.R. 1.97, 1.98 and MPEP 609 because there is no translation of art references JP 2000-514053, JP 2002-515424, and JP 11-507361.

Applicants respectfully disagree as the relationship of these references to other English language references and/or references for which an English Abstract was provided is clearly outlined in the 1449 Form as well as the Information Disclosure Statement. Specifically, JP 2000-514053 (reference AF of the IDS) is indicated to be related to U.S. Patent 6,623,752 (reference AQ of the IDS) which is in English; JP 2002-515424 (reference AI of the IDS) is indicated to be related to WO 99/59558 (reference AH of the IDS) for which an English language abstract is provided; and

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JP 11-507361 (reference AM of the IDS) is indicated to be related to WO 96/40139 which is in English. Accordingly, consideration of these English language teachings as being related to JP 2000-514053, JP 2002-515424, and JP 11-507361 is respectfully requested.

**II. Rejection of Claims 9 and 10 under 35 U.S.C. 112, second paragraph**

Claims 9 and 10 have been rejected under 35 U.S.C. 112, second paragraph. Specifically, the Examiner suggests that there is insufficient antecedent basis in claim 1 for "(meth)acrylic polymer", "adhesive layer" and "acrylic polymer". Further, claim 10 is suggested to be unclear as attempting to exclude a claimed element, namely (meth)acrylic polymer.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 1 to provide antecedent basis for the adhesive layer. Further, Applicants have amended claims 9 and 10 to clarify that the adhesive layer contains a (meth)acrylic polymer and may further contain an acrylic polymer different from the (meth)acrylic polymer. Support for these amendments is provided in the specification at page 8, lines 20-25. No new matter is added by these amendments.

Withdrawal of these rejections is respectfully requested in light of these amendments.

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**III. Rejection of Claims 1-9 and 11-12 under 35 U.S.C.**

**102(b)**

Claims 1-9 and 11-12 have been rejected under 35 U.S.C. 102(b) as being anticipated by Terahara et al. (WO 2002/038189). The Examiner suggests that Terahara et al. teaches an adhesive pharmaceutical preparation for transdermal absorption of drugs comprising a polymer, drug, penetration enhancers, plasticizers, rubber polymers, releasing paper (for transdermal patch), resins, antioxidants, filler and many other components for transdermal patches that are known in the art. Further, the Examiner suggests that Terahara teaches a specific example of a transdermal patch for pergolide mesilate.

Claims 1-9 and 11-12 have also been rejected under 35 U.S.C. 102(b) as being anticipated by Arth et al. (U.S. Patent 6,461,636). The Examiner suggests that Arth et al. teaches a composition and transdermal therapeutic system (TTS) for the delivery of pergolide. The Examiner suggests that the TTS is a transdermal plaster applied to the skin with an impermeable covering layer, a removable layer and a matrix containing the active substance or a reservoir of the active substance with a semi-permeable membrane.

Applicants respectfully traverse these rejections.

At the outset, it is respectfully pointed out that claim 1 has been amended to recite a transdermal preparation

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containing 9-50 mass% pergolide and/or a pharmaceutically acceptable salt thereof in an adhesive layer containing 10-70 mass% styrene-isoprene-styrene block copolymer. Support for this amendment is provided in the specification at page 15, line 25, page 19, lines 7-8 and page 24, line 8.

Neither of the cited references teach or suggest a transdermal preparation containing 9-50 mass% pergolide and/or a pharmaceutically acceptable salt thereof in an adhesive layer containing 10-70 mass% styrene-isoprene-styrene block copolymer (SIS). Instead, Terahara et al. discloses an adhesive patch containing 4.7% SIS while Arth teaches pergolide mesilate concentrations of 1.47-1.7% in the examples and 0.5% to less than 5% in the claims.

New claims 13-22, supported by teachings throughout the specification, see e.g. pages 10-12, are also novel over teachings of Terahara et al. and Arth et al. as these reference neither teach or suggest reduction of the side effects afflicted by pergolides by achieving a plasma AUC ratio of pergolide or the pharmaceutically acceptable salt thereof to at least one metabolite thereof of 1:0.5 to 1:5 as claimed.

Thus, since neither of the references teach or suggest all the limitations of the instant claims, these references cannot anticipate the claimed invention.

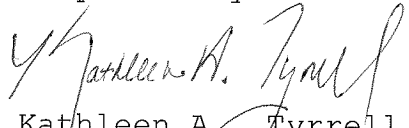
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Withdrawal of these rejections under 35 U.S.C. 102(b)  
is therefore respectfully requested.

**IV. Conclusion**

Applicants believe that the foregoing comprises a full  
and complete response to the Office Action of record.  
Accordingly, favorable reconsideration and subsequent  
allowance of the pending claims is earnestly solicited.

Respectfully submitted,

  
Kathleen A. Tyrrell  
Registration No. 38,350

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Licata & Tyrrell P.C.  
66 E. Main Street  
Marlton, New Jersey 08053

(856) 810-1515